



VERMONT AGENCY OF HUMAN SERVICES
DEPARTMENT OF MENTAL HEALTH

Electroconvulsive Therapy (ECT)
Standards to be Monitored

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Table of Contents

Introduction 3

Indications for Use of Electroconvulsive Therapy (APA p 5-25) 4

Pre-Electroconvulsive Therapy Evaluation (APA p 77-79) 4

Use of Electroconvulsive Therapy in Special Populations (APA p 31-58) 5

Informed Consent for Electroconvulsive Therapy 6

Education and Training in Electroconvulsive Therapy (APA p 225-233)..... 6

Location, Equipment, and Supplies (APA p 117-124) 9

Treatment Procedures (APA p 125-195)..... 10

Treatment Following Index ECT Course (APA p 201-216)..... 12

Documentation (APA p 217-220)..... 13

References 15

Introduction

The Department of Mental Health (DMH), in compliance with Title 18, Chapter 177, Section 7408, has adopted standards to govern the practice of electroconvulsive therapy (ECT). These standards will be applied to hospitals that provide electroconvulsive therapy in the state of Vermont. DMH has selected *The Practice of Electroconvulsive Therapy, Recommendations for Treatment, Training, and Privileging*, Second Edition, published by the American Psychiatric Association (APA) as the basis of the standards of practice.

The Department of Mental Health is committed to ensuring that practitioners administering ECT in Vermont follow the most recent treatment guidelines published by the American Psychiatric Association's Task Force on ECT. Vermont hospitals which provide ECT agree to follow the APA's Guidelines regarding its administration. While every entity delivering ECT is expected to operate within these guidelines as the standard of practice, DMH has selected a sub-group of these guidelines to specifically monitor.

These standards to be monitored are intended to assist with the identification of important clinical areas regarding ECT administration. They will be used to guide the Department of Mental Health's oversight and monitoring of facilities administering electroconvulsive therapy. These standards are not intended to be all inclusive. The APA's *Practice of Electroconvulsive Therapy* shall be referred to when additional information is required. APA page numbers are referenced to help locate specific topic areas.

These standards have been updated from the March 2018 version to correct an errant comment.

Indications for Use of Electroconvulsive Therapy (APA p 5-25)

Principal Diagnostic Indications

For major diagnostic indications, there is either compelling data supporting the efficacy of ECT or a strong consensus in the field supporting the use of ECT.

Major Depression

- Major Depressive Disorder- all subtypes
- Bipolar Affective Disorder- Most recent episode, mixed type

Mania

- Bipolar Affective Disorder- most recent episode, Manic type

Schizophrenia

- Psychotic symptoms – abrupt onset
- Catatonic symptoms
- History of a favorable response to ECT
- Schizophreniform disorder
- Schizoaffective disorder
- Psychotic disorders not otherwise specified
- When clinical features are similar to those of other major diagnostic indications

Other Diagnostic Indications

For other diagnostic indications, standard treatment alternatives must be considered as the primary intervention before a recommendation for ECT.

Psychiatric Disorders

- Psychiatric disorders other than the principal diagnostic indications is not adequately substantiated and shall be carefully justified in the clinical record.

Non-Psychiatric Disorders

ECT may be of benefit in the treatment of the following disorders:

- Delirium of various etiologies, including toxic and metabolic.
- Chronic intractable pain
- Delirium
- Parkinson's disease
- Neuroleptic malignant syndrome
- Intractable seizure disorder

Pre-Electroconvulsive Therapy Evaluation (APA p 77-79)

Hospital policy shall determine the specific components of the routine pre-ECT evaluation. The following shall be included at a minimum:

- A psychiatric history and examination -includes review of the effects of any prior ECT treatment course.
- Cognitive assessment including a mini-mental status exam and Montgomery-Asberg Depression Rating Scale to determine both cognitive (memory) and depressive symptoms baseline. This will include assessment of memory impairment from any previous course of treatment with ECT.
- A medical evaluation to determine fitness to go through anesthesia as well as ECT treatment
- Including an assessment of the teeth and mouth to identify any dental risk factors
- Laboratory tests as indicated
- An evaluation by an individual privileged to administer ECT summarizing indications and risks, and suggesting any additional evaluative procedures, alterations in ongoing medications, or necessary modifications in ECT technique.
- Evaluation by an anesthesiologist
- Assessment to include patient's previous exposure to anesthesia, review of any side effects, and allergies

Medical evaluation of risk factors shall be carried out prior to ECT (APA p 27-29)

- Unstable or severe cardiovascular conditions
- Aneurysm or vascular malformation
- Increased intracranial pressure
- Recent cerebral infarction
- Pulmonary condition
- Intracranial space occupying lesion
- Serious musculoskeletal problems

Use of Electroconvulsive Therapy in Special Populations (APA p 31-58)

Neurologic Disorders

Patients with increased intracranial pressure have substantially elevated risk with ECT; its use must be justified in terms of risk/benefit considerations.

Cardiovascular Disorders

Consultation with a physician who has expertise in the assessment and treatment of cardiovascular diseases shall be considered if the pre-ECT evaluation suggests significantly increased cardiovascular risk.

Other Disorders

- Patients with unstable or insulin-dependent diabetes mellitus shall be considered for medical consultation.
- Patients with clinically significant hyperthyroidism shall receive specialty consultation.
- Specialty consultation shall be used with pheochromocytoma
- Patients with recent or evolving retinal detachment shall undergo ophthalmologic consultation.

Pregnancy

- In pregnant patients, obstetric consultation shall be obtained prior to ECT.
- At facilities administering ECT to pregnant women, resources for managing obstetric and neonatal emergencies shall be readily accessible.

Cognitive Disorders

- Consultation with a memory disorder specialist may be indicated for patients with pre-existing cognitive impairments prior to initiation of ECT.
- Detection and monitoring of the presence of ECT-related cognitive impairment, orientation and memory function shall be assessed prior to ECT and periodically throughout the ECT course. If such impairment occurred in the past, then the treatment plan for a future course of ECT shall be modified accordingly to minimize chances of such problems as the person experienced in a prior course.
- Based on assessment, potential treatment modifications include changing from bilateral to right unilateral electrode placement, decreasing the intensity of electrical stimulation, increasing the time interval between treatments, altering the dosage of medications, or, if necessary, terminating the treatment course.

Informed Consent for Electroconvulsive Therapy

All facilities must use the Informed Consent guidelines set by the Vermont Department of Mental Health. The consent forms are available online: http://mentalhealth.vermont.gov/sites/dmh/files/documents/Manuals/2018_ECT_Informed_Consent_Package.pdf

Hospitals providing ECT will address specific to informed consent in special circumstances, such as medical guardianship and advanced directive, in their policies and procedures.

Advance Directives

- Patients retain the right to refuse ECT treatment. If the patient has an Advanced Directive, the agent must be notified of the refusal, even if the Advanced Directive includes reference to ECT. If the Advance Directive includes a Ulysses clause regarding ECT, the agent must be notified and, if the agent consents to the ECT, the treatment can be given even if the patient objects.

Medical Guardianship

- Documentation of medical guardianship must be present in the patient's medical record.
- Medical guardians with specific authorization have the authority to give consent for ECT treatment.
- If a person who has a medical guardian refused treatment, the guardian must be notified. The guardian must obtain permission from the court in order to override the objection and consent to the ECT.

Education and Training in Electroconvulsive Therapy (APA p 225-233)

Responsibilities of the ECT Treatment Team (APA p 113-115)

Each facility is responsible for designating required tasks to the appropriately qualified staff. These responsibilities shall be clearly defined in the policy and procedure manual.

ECT Psychiatrist

The ECT psychiatrist shall maintain overall responsibility for the administration of the treatment. The ECT psychiatrist will be responsible for:

- assessing the patient before beginning ECT,
- ensuring that all pre-ECT evaluations have been completed,
- determining that ECT is still indicated,
- ensuring that ECT is delivered in accordance with policies and procedures,
- instituting modifications in ECT as indicated, and
- ensuring proper documentation of evaluations and treatment results.

Anesthesia Provider

Responsibilities for the anesthesia provider generally include:

- managing the airway,
- administering ultra-brief anesthetic and relaxant agents,
- monitoring cardiopulmonary functioning, and
- managing acute adverse events.

ECT Nurse or Assistant

This person is usually a registered nurse (RN) but may also be a licensed practical nurse (LPN) or an assistant with ECT training and experience. Responsibilities shall be consistent with training and clinical competence and generally include assisting the ECT psychiatrist and the anesthesia provider with duties such as:

- coordinating treatment logistics,
- readying the treatment area for ECT, including checking the proper functioning of equipment (e.g. suction, physiological monitoring equipment, etc.),
- assisting patients to and from treatment area,
- applying stimulus and monitoring electrodes, and
- monitoring vital signs.

Additional duties for ambulatory ECT patients may include assessing patients before each ECT treatment and delivering post recovery care.

Recovery Nurse

This person is a registered nurse whose responsibilities include:

- monitoring of vital signs, pulse oximetry, ECG, and mental status,
- administering oxygen and intravenous fluids,
- provision of suctioning, and
- management of postictal disorientation and agitation.

Responsibility of the Facility (APA p 113-115)

The director of each such facility, or his or her designee, shall appoint a psychiatrist privileged to administer ECT as the Medical Director of the Program, to be responsible for maintaining up-to-date policies and procedures regarding ECT, for ensuring that these policies and procedures are met, and for seeing that appropriate staffing, equipment, and supplies are available.

Each such facility shall implement an ECT quality improvement program. All persons involved in the delivery of ECT shall be privileged in the performance of clinical ECT-related duties by the organized medical staff of the facility under whose auspices ECT will be administered.

Facilities shall ensure that psychiatrists and staff members who are privileged in ECT administration should supervise psychiatry residents involved in the delivery of ECT and management of patients receiving ECT.

Privileging in ECT (APA p 241-245)

Each member of the ECT treatment team, as defined in Chapter 9 (APA p 109-115), shall be clinically privileged to practice his or her respective ECT-related duties or be otherwise authorized by law to do so. Such privileging shall be carried out according to procedures established by the organized medical staff of the facility or its equivalent under whose auspices ECT is administered.

The medical director/Chair of the Department of each facility shall ensure that privileges to administer ECT are granted only to psychiatrists with demonstrated proficiency to deliver ECT in a safe and effective manner. The medical director, with the assistance of appropriate individuals, shall develop a formal written plan for provision and maintenance of ECT privileges. This plan shall designate those responsible for determining whether privileging criteria have been met. Proceedings of all privileging actions shall be documented.

The applicant's education, training, experience, and history of privileging in ECT shall be reviewed by the committee designated for this purpose to determine whether the applicant is competent to practice ECT. If so, clinical ECT privileges may be granted following satisfactory administration of ECT as observed by a designated in-house evaluator or, if necessary, by an outside consultant.

A practitioner with insufficient knowledge in ECT procedures shall undertake appropriate training. Privileges may then be awarded after completion of

- the prescribed training experience,
- the local orientation process, and
- demonstration of proficient administration of ECT in the local setting.

Reassessment of privileges shall occur at least every 2 years or as specified by policies of the institution. Policies developed by the facility for this purpose shall contain the following components:

- Use of a quality improvement program to monitor selected aspects of ECT treatment team performance, review of any apparent deficits, and institution of corrective action;
- Ongoing monitoring of number of ECT treatments administered by treating psychiatrists, so that individuals whose practice becomes inactive can be given the opportunity to demonstrate use of proficient technique on resuming an active clinical role; and
- Demonstration of CME experience in ECT-related areas.

Continuing Education Programs

Regular continuing education and training opportunities in ECT shall be available for all ECT treatment team members in order remain informed about best-practices in ECT. Continuing education in the form of conferences, case discussion, and consultation is expected for all providers to remain current in their practice.

Location, Equipment, and Supplies (APA p 117-124)

Treatment Site and Equipment

The treatment site shall be conducive to the delivery of ECT treatment for both the patient and staff. The treatment site shall include separate areas for waiting, treatment, and recovery. If outpatient ECT treatment is provided, there shall also be space identified for patients and those accompanying the patient during the post recovery period.

Policies shall identify where ECT related equipment and supplies are stored within the treatment site. Staff responsibilities regarding the treatment site shall be included in the policy and procedure manual. Patient medical records shall be readily accessible to the ECT treatment team during treatment. Practices shall cover storage and staff access to medications within the ECT treatment area.

Since ECT differs from other “typical” operative procedures, hospitals that designate general operating rooms, surgical suites, and/or common recovery rooms for ECT treatment shall identify any additional equipment that is specific to the delivery of ECT and shall be available during treatment. When such treatment sites are used, providers shall delineate any additional steps that may be needed to assure patient privacy.

When treating patients who are at significantly increased risk of musculoskeletal injury (e.g. severe osteoporosis) or when using nondepolarizing muscle relaxant agents (e.g. curare, atracurium, mivacurium, rocuronium), it is recommended that a peripheral nerve stimulator be available to ensure the adequacy of muscle blockade before delivering the electrical stimulus. A defibrillator shall be readily available. Access to a backup ECT device and additional cables is suggested. Staff responsibilities relating to equipment shall be delineated including its availability in the treatment area, safety checks and general care and maintenance.

The treatment site shall contain sufficient quantities of required and optional equipment, medications and supplies to administer ECT safely (APA p 118).

Providers shall identify the equipment to be available in administering ECT.

Treatment Area

Standard equipment in the treatment area includes:

- stretcher or bed with side rails and the capacity to raise both the head and feet,
- automatic or manual blood pressure monitoring device,
- stethoscope,
- ECT device with built-in EEG monitoring,
- ECG monitoring equipment,
- sphygmomanometer cuff to permit detection of ictal motor duration,
- pulse oximeter,
- oxygen delivery system,
- suction apparatus,
- intubation set for managing airways, and
- reflex hammer.

The treatment area shall also contain equipment for intubation, seizure induction (brief pulse waveform ECT device), physiologic monitoring including EEG, and resuscitation.

Recovery Area

The recovery area shall also contain ECG monitoring and pulse oximetry devices. Equipment shall be available in both the ECT treatment area and the recovery area to

- provide suction;
- deliver intermittent positive-pressure oxygen; and
- monitor vital signs, including cardiac rhythm and hemoglobin oxygen saturation.

Medications

Medications used during the administration of ECT shall be located within the treatment site. (APA p 118-119, 122-123). Pharmacologic agents that may be required during ECT treatment shall be identified. Such medications include:

- primary anesthetic agent,
- primary muscle relaxant,
- an anticholinergic agent,
- medications for first-line management of arrhythmias, hyper- or hypotension, and cardiac arrest,
- medications for the initial management of severe bronchospasm or anaphylactic shock, other agents for managing status epilepticus,
- anti-nausea medications, and
- non-narcotic analgesics.

Supplies (APA p123-124)

The treatment area shall have sufficient quantities of supplies to induce analgesia, monitor the physiologic functions (including seizure activity) and provide ventilation and resuscitation.

Necessary supplies include:

- bite blocks,
- infusion sets,
- intravenous fluids,
- masks for oxygen therapy,
- oro and nasopharyngeal airways,
- endotracheal tubes,
- suction catheters,
- syringes and syringe needles in assorted sizes,
- electrode gel or paste,
- monitoring electrode pads and leads,
- stimulus and monitoring cables for ECT device,
- recording paper for monitoring use,
- alcohol pads,
- material to prepare stimulus and monitoring electrode sites,
- gauze pads and tape in assorted sizes,
- disposable gloves, and
- containers for disposal of sharps and clinical waste.

Treatment Procedures (APA p 125-195)

ECT Devices (APA p 139-142)

Waveform Characteristics

A brief pulse stimulus is the standard of care. Because of the potential aggravation of cognitive side effects and the lack of evidence of any therapeutic advantage, the continued use of sine wave stimulation is not justified.

Treatment Parameters

Practitioners shall have an established treatment protocol for selecting stimulus dosage that is specific to the patient's individualized treatment plan.

Ictal Motor Activity

Seizure duration shall be documented at each treatment and shall be monitored by timing the duration of convulsive movements.

Ictal EEG Activity

Scalp electroencephalographic (EEG) monitoring shall be carried out on at least a one-channel basis.

Standard of Care for Anesthesia Monitoring

ECG monitoring shall begin prior to anesthesia induction and continue until spontaneous respiration resumes and any treatment-associated ECG abnormalities have resolved. There shall be capacity to provide a paper copy of ECG activity in the event that later consultation is necessary.

Systolic and diastolic blood pressure, as well as heart rate or pulse, shall be measured before anesthetic induction and at intervals throughout the procedure. Pulse oximetry shall be used during ECT.

Frequency and Number of Treatments (APA p 174- 177)

It is the responsibility of the provider to determine the frequency and number of treatments as indicated by the severity of illness and by the relative benefits and risks of ECT treatment.

Providers shall address the following:

- Frequency of treatments, including the usual number of weekly treatments (commonly scheduled three times per week in the United States), variations in frequency, and review of frequency, based on patient response.
- Number of treatments, including the usual number of treatments for specific types of psychiatric disorders (e.g. 6-12 treatments for major depression), changes in the course of treatment based upon patient response, clinical improvement, and assessment of cognitive adverse effects.

All of these factors contributing to the course of treatment will be discussed with the patient.

Evaluation of Treatment Outcomes (APA p 197-202)

Therapeutic Response

Each treatment plan shall indicate specific criteria for meeting patients' therapeutic goals, whether that may be clinical improvement and/ or remission.

Clinical Assessments

Clinical assessments shall be performed by the attending physician or designee and documented prior to ECT and after every one or two ECT treatments, preferably at least 24 hours after the treatment.

Clinical rating instruments will be routinely utilized to monitor treatment outcomes and identify changes in symptoms over the ECT course. Standardized scales in use at this time include the Montgomery-Asberg Depression Rating Scale and the Global Impressions Scale.

Adverse Effects (APA p 199-202)

Cognitive Changes

Evaluation of cognitive function will be assessed to identify changes in orientation and memory through the use of objective evaluation and by subjective report. Assessment shall be gathered to determine baseline functioning and shall be repeated at least weekly during the Index course of treatment and will include a mini mental status exam.

When possible, cognitive assessment shall be performed at least 24 hours after an ECT treatment. The presence and severity of disorientation, anterograde amnesia, and retrograde amnesia shall be monitored in terms of both objective findings and self-report. This evaluation shall consist of bedside assessment of orientation and memory (both retention of newly learned material and recall of recent and remote events) and/or administration of formal neuropsychologic measures. A five-point Likert scale will be used by all facilities to evaluate patients' subjective self-report of changes in memory.

If orientation and/or memory deteriorate during an ECT course, modifications to the ECT procedure shall be considered. If such effects persist after completion of the ECT course, a plan shall be made for post-ECT follow-up assessment which will include appropriate referrals to specialists and treatment providers to address memory changes.

Other Adverse Effects

Any sudden onset of new risk factors or worsening of previously identified risk factors shall be evaluated before the next ECT treatment. In this regard, patient complaints shall be considered carefully.

Any serious medical event occurring during the course of ECT will be reported to the Department of Mental Health. Please see the *Designated Hospital Critical Incident Reporting Requirements*, found on the Department's website.

Treatment Following Index ECT Course (APA p 201-216)

Indications for Continuation ECT

If the patient has a history of illness that has been responsive to ECT and one of the following has occurred:

- Pharmacotherapy alone has not been effective,
- Pharmacotherapy cannot be safely administered, and
- The patient prefers treatment with ECT.

Pre-ECT Evaluation for Continuation ECT (APA p 210)

Repeated informed consent will be obtained at least every 12 treatments or every 6 months, whichever comes sooner. Prior to each continuation ECT treatment, pre-ECT evaluation will include standards required for Index course of treatment

Documentation (APA p 217-220)

Facility Responsibilities

It is the responsibility of the facility's medical director (or medical staff, if no such individual is defined) to ensure adequate documentation regarding ECT.

Prior to an Index ECT Course

The ECT psychiatrist shall confirm that the following documentation is included in the patient's clinical record (a checklist or summary format is encouraged):

- Reasons for ECT referral,
- Mental status, including baseline information,
- Signed consent document,
- Statement covering other elements of the informed consent process,
- Pertinent laboratory results,
- Consultation reports as indicated, and
- Discussion of any substantial alterations planned in the ECT procedure.

Between ECT Treatment Sessions

Notes by the attending physician or designee shall be entered in the patient's clinical record at least every two treatments during an index ECT course and shall contain information about the presence or lack of a therapeutic response and any other substantive change. Notes describing the presence or absence of adverse cognitive effects shall be entered into the record at least weekly.

Documented justification shall be provided before exceeding a specified maximum number of treatments (set by each facility) in an index ECT course (see APA sections 8.4 and 11.11.2).

With continuation or maintenance ECT, documentation of the presence or absence of beneficial response shall occur either prior to each treatment or at least monthly if the patient is stable and treatments occur more than twice per month (see APA Section 13.2.2.2.). The presence or absence of adverse cognitive effects shall be noted at least every three treatments.

When a continuation or maintenance ECT series is extended by an initial or subsequent 6-month period, the rationale shall be documented (see APA Section 13.2.3.3. and 13.3.2.).

At the Time of Each ECT Treatment Session

For each treatment session, at least the following information shall be documented in the patient's clinical record:

- Baseline vital signs;
- Medication, including dosage, given before entering the treatment room;
- Note from the anesthetist describing the patient's condition while in treatment/recovery area;
- A note from the ECT psychiatrist or anesthetist covering any major alterations in risk factors or presence of adverse effects or complications, including actions taken and recommendations made (where applicable);
- Medication, including dosage, given in treatment and recovery areas;
- Stimulus electrode placement;
- Stimulus parameter settings for each stimulus;
- Seizure duration and/or other indices of seizure adequacy (noting whether motor or electroencephalographic);
- Vital signs taken in treatment room and recovery area; and
- Notes from the recovery nurse or the anesthesia provider documenting occurrence and management of any complications during recovery and patient's condition on leaving the recovery area.

A "time-out" shall be implemented prior to the initiation of each treatment session in accordance with Joint Commission guidelines. The time out shall include verification of the patient's identity, and agreement on the procedure to be done. The time out shall be briefly documented in the patient's medical record.

Following Completion of an Index ECT Course or a Continuation/Maintenance ECT Series

The attending physician or designee shall enter the summary of overall therapeutic outcome and adverse effects experienced as a result of ECT course or series and rationale for specific choice of endpoint in the clinical record. A plan for post-ECT clinical management and plans for follow-up of adverse effects if any shall be identified.

References

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